

EXHIBIT 36



■ ARTHROPLASTY

Forced-air patient warming blankets disrupt unidirectional airflow

A. J. Legg,
A. J. Hamer

From Northern
General Hospital,
Sheffield, United
Kingdom

✉ A. J. Legg, BSc, MBChB,
MRCS, ST6 Orthopaedics
✉ A. J. Hamer, MD, FRCS(Orth),
Consultant Orthopaedic
Surgeon
Northern General Hospital,
Herries Road, Sheffield S5 7AU,
UK.

Correspondence should be sent
to Mr A. J. Legg; e-mail:
drandrewlegg@hotmail.com

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We have recently shown that waste heat from forced-air warming blankets can increase the temperature and concentration of airborne particles over the surgical site. The mechanism for the increased concentration of particles and their site of origin remained unclear. We therefore attempted to visualise the airflow in theatre over a simulated total knee replacement using neutral-buoyancy helium bubbles. Particles were created using a Rocket PS23 smoke machine positioned below the operating table, a potential area of contamination. The same theatre set-up, warming devices and controls were used as in our previous study. This demonstrated that waste heat from the poorly insulated forced-air warming blanket increased the air temperature on the surgical side of the drape by $> 5^{\circ}\text{C}$. This created convection currents that rose against the downward unidirectional airflow, causing turbulence over the patient. The convection currents increased the particle concentration 1000-fold (2 174 000 particles/ m^3 for forced-air warming vs 1000 particles/ m^3 for radiant warming and 2000 particles/ m^3 for the control) by drawing potentially contaminated particles from below the operating table into the surgical site.

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Ultraclean unidirectional airflow has been shown to reduce significantly the risk of infection in lower limb joint replacement.^{1–4} In recent years, patient warming has also been shown to afford significant benefit. Hypothermia causes peripheral vasoconstriction, which reduces the delivery of oxygen to soft tissues; this in turn impairs the oxidative killing of bacteria by neutrophils and lessens the strength of wound healing by reducing the deposition of collagen.⁵ By increasing blood flow and the oxygen tension in the tissues, the risk of surgical site infection, cardiovascular events, peri-operative pain and bleeding is reduced.⁶ In addition, the maintenance of a patient's normal core temperature reduces the duration of post-operative recovery and hospital stay.^{5–8}

We reported with a particular arrangement in the operating theatre set-up, waste heat from forced-air warming can increase the particle concentration and temperature over the surgical site.⁹ This implies that the downward unidirectional airflow is disrupted by the waste heat generated, although the mechanism of airflow disruption was unclear. The increased concentration of particles over the surgical site is of concern as it may transport bacteria. The purpose of this study was to visualise the airflow over the surgical site to see if the additional particles came from a potentially contaminated area.

Materials and Methods

We simulated the theatre set-up (Fig. 1) that we use for a total knee replacement at the Northern General Hospital (Sheffield, United Kingdom) with the exception that, in an attempt to isolate the effect of forced-air warming, there was only a single surgeon in the Howorth ExFlow 90 enclosure (Howorth Air Technology, Bolton, United Kingdom). A mannequin was placed supine on the operating table and a single knee replacement non-porous exclusion drape was hung vertically from the Howorth enclosure. The drape extended to the floor over the table and the opposite limb, so that only the knee being operated on was exposed. The enclosure walls extended down to within 1 m of the theatre floor. This created a confined area that extended the unidirectional airflow below the site of surgery and kept unscrubbed personnel out of the enclosure. The single surgeon wore a standard theatre gown, hood, mask and body exhaust hose that was attached outside the enclosure. Validation and verification checks of the ventilation system showed that it conformed to the requirements of the Health Technical Memorandum (HTM) 2025.¹⁰

We compared two warming devices and a control (no warming device). The two devices were a torso forced-air warming device (Bair Hugger; Arizant, Wakefield, United Kingdom)

Bair Hugger
Exhibit 96
Date: 11-18-16
Richard G. Stirewalt
Stirewalt & Associates

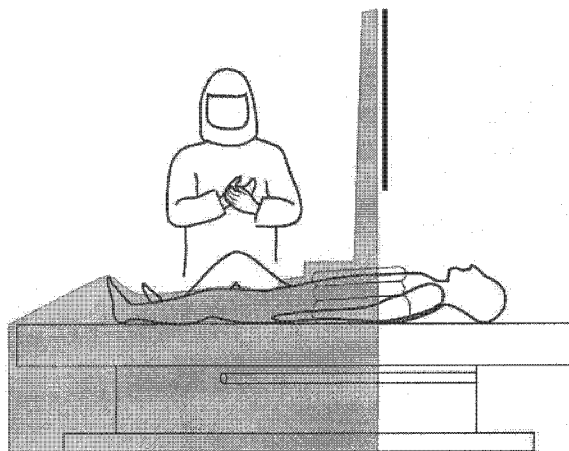


Fig. 1

Diagram showing the theatre set-up.

and a torso radiant warming device (HotDog, Eden Prairie, Minnesota). To see if particle entrainment occurred from a potentially contaminated area, a continuous flow of $0.3\ \mu\text{m}$ glycerol tracer particles, created by a Rocket PS23 smoke machine (Pea Soup Ltd, Ingleby Barwick, United Kingdom), was introduced through a 1 m-long fenestrated tube secured below the table at the level of the surgeon's knees (Fig. 1). The smoke machine was connected to the fenestrated tube by a long hose to allow the particles to cool before entering the enclosure. All investigations were undertaken over one day, in a single theatre, with the same equipment and investigators.

Experimental design. The drape temperature, particle concentration and particle visualisation were each assessed five times for each warming device and control. The mean drape temperature and particle concentration were then calculated.

Airflow visualisation. The airflow was visualised using neutrally-buoyancy helium soap bubbles, produced by a bubble generator (Sage Action, Ithaca, New York) and a high-intensity light source. The bubbles were produced using a mixture of helium, air, detergent, and a centripetal bubble size classification filter to produce neutrally buoyant bubbles of approximately 4 mm diameter. Photographs were taken using a digital camera (D300; Nikon, Melville, New York) with a shutter speed of 0.25 s to allow the path of the bubbles to be seen. Neutrally buoyant helium bubbles enable the easy visualisation of streamlines and pathlines in flow fields that are not easily seen using traditional methods.¹¹

Particle sampling. The particle concentration over the surgical site was measured using a HandiLaz handheld particle counter (Particle Measuring Systems, Boulder, Colorado). This instrument has a sample volume of $0.084\ \text{m}^3$ and can measure particles of $> 0.3\ \mu\text{m}$.

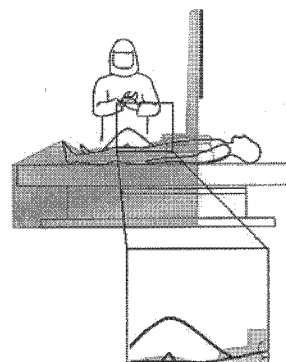
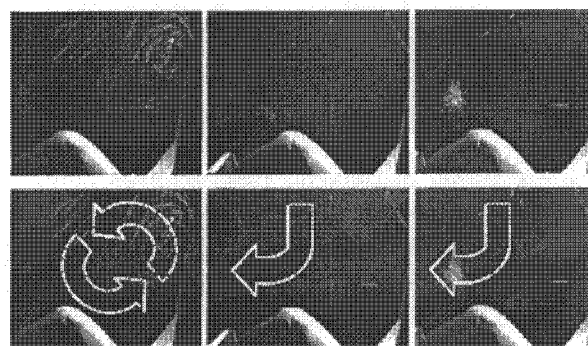


Fig. 2a



Forced-air warming Radiant warming Control

Fig. 2b

Figure 2a – diagram showing the area in which the airflow was assessed. Figures 2b – example photographs showing the visualisation of airflow using forced-air warming (left), radiant warming (centre) and none (right). The lower images are illustrated to emphasise the direction of airflow.

Drape temperature. The drape temperature was measured at the same point on each occasion in line with the exposed flexed knee using a digital temperature probe taped on to the exclusion drape on the left side of the surgeon. This was compared with the temperature of the theatre outside the Howarth enclosure, which was kept as stable as possible.

Statistical analysis. All data were evaluated using two-tailed *t*-tests. Statistical significance was assumed at *p*-values < 0.05 .

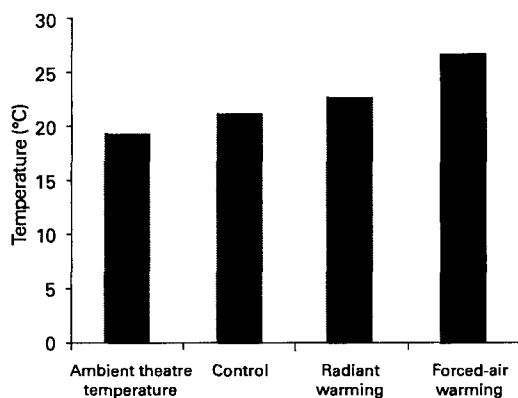
Results

The theatre temperature remained stable throughout the entire investigation at 19.2°C (SD 0.36).

Airflow visualisation. Unidirectional airflow was significantly disrupted when forced-air warming was used. Convection currents were set up within seconds of the forced-air warming system starting up: the bubbles rose approximately 1 m above the operating site, moved away from the drape, and then fell directly on to the surgical site before rising again to start the next cycle (Fig. 2).

Table I. Particle entrainment concentration

Warming scenario	Concentration (particles/m ³)
Control	2000
Radiant warming	1000
Forced-air warming	2 174 000

**Fig. 3**

Bar chart showing the theatre and drape temperatures for the various types of warming.

When the radiant warming device or the control was used there was no disruption of unidirectional airflow (Fig. 2). The bubbles moved away from the surgical site, then dispersed below the theatre table and out of the Howorth enclosure.

Particle entrainment. Forced-air warming significantly increased the concentration of particles over the surgical site (2 174 000 particles/m³) compared with both the radiant warming device (1000 particles/m³) ($p = 0.0002$) and the control (2000 particles/m³) ($p = 0.0002$) (Table I). However, there was no significant difference between the radiant warming device and the control ($p = 0.1522$).

Vertical surgical drape temperature. Forced-air warming significantly increased the temperature of the drape compared with both the radiant warming device and the control, at increases of 4.3°C ($p = 0.0001$) and 5.4°C, respectively ($p = 0.0001$). However, there was no significant difference between the radiant warming device and the control (1.1°C; $p = 0.0539$) (Fig. 3).

Discussion

Unidirectional vertical airflow passes through high-efficiency particulate air (HEPA) filters, filtering particles of 0.3 µm with 99.97% efficiency to create a bacteria-free source of air.¹² The Howorth enclosure, when combined with vertical unidirectional airflow, aims to create within a designated space an entire body of air that has a uniform velocity and direction. It is designed to minimise the

entrainment of particles, which are known to transport bacteria,³ from outside the Howorth enclosure and from below the operating table. This is enhanced by the plenum effect of the pressure inside the theatre being greater than that outside, which creates exponential airflow and a net movement of air out of the theatre.

Unidirectional HEPA filtered airflow has been the standard requirement in joint replacement surgery for many years.¹⁻⁴ In addition, warming the patient with forced air has been shown to have significant benefits, including the reduction of surgical site infection, and forms part of the guidelines from the National Institute for Health and Clinical Excellence in the United Kingdom.^{5-8,13} However, it had not previously been established whether warming the patient with forced air has any effect on unidirectional airflow.

In our experiment, the clearest interference with unidirectional airflow occurred when the mannequin was warmed with the forced-air device. Convection currents were established within a short period of time. Waste heat from the poorly insulated device warmed the drape and increased the air temperature over the surgical site. The warmed air rose against the downward unidirectional airflow, reaching a peak approximately 1 m above the surgical site at which point the air reached the cooler unidirectional airflow and then flowed back on to the operation site. This process was then repeated, creating convection currents. Once this cycle was established, particles were entrained in the airflow from below the table, drawn up into the vortex to fall on to the surgical site. Unidirectional airflow was not disrupted when either the radiant warming device or the control was used. There was little or no waste heat created from the radiant device, which was well insulated on the side not in contact with the patient.

It does not appear that the forced-air warming device itself blows potentially contaminated warm air directly into the Howorth enclosure. The device heats the drape covering it, leading to the creation of convection currents that meet the downward unidirectional airflow, causing turbulence.

We suggest that if the forced-air warming device was as well insulated on the surface that was not in contact with the patient as occurs with the radiant warming device, waste heat might not have warmed the vertical drape and created the convection currents.

If the theatre is set up as shown in Figure 1, waste heat significantly disrupts unidirectional airflow. Therefore, a warming device that disperses heat away from the patient should not be used. In other words, the surface not in contact with the patient needs to be well-insulated. If the theatre set-up uses Howorth wall extensions or a vertical drape between the surgical field and the anaesthetist, an enclosed environment is created. The potential benefits of this set-up are the exclusion of personnel from the interior of the enclosure. If the wall extensions and vertical drape that exclude the anaesthetist are not in place, the production of waste heat may not be as important because the air could leave the enclosure more easily.

The benefits of unidirectional airflow have been proven, as have the significant benefits of patient warming. Therefore it is important that both continue to be used. However, the set-up of the theatre and the effect of waste heat need to be taken into consideration, as they may have a detrimental effect on the unidirectional airflow and thus, potentially, the sterility of the surgical site.

This study does not show that forced-air warming increases the risk of infection – only that in certain types of theatre set-up it can significantly disrupt unidirectional airflow and draw particles from the potentially contaminated area below the sterile surgical field. This is a concern.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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